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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,462	09/11/2003	Keith G. Lurie	016354-005211US	4944

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EXAMINER

RAGONESE, ANDREA M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,462

Applicant(s)

LURIE, KEITH G.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3, 9, 14-15 and 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Biondi et al. (US 5,377,671). Biondi et al. discloses a method for treating a person "with compromised respiratory function," such as suffering from head trauma associated with elevated intracranial pressures (column 1, lines 16-19) by:

- coupling a mechanical ventilator to a person, as shown in Figure 1;
- actively delivering a positive pressure breath to a person using the ventilator (column 3, lines 10-31);
- actively extracting respiratory gases from the person's airway following the positive pressure breath using the mechanical ventilator to create an intrathoracic vacuum to lower pressures in the venous blood vessels that transport blood out of the head, which inherently reduces intracranial pressures (Abstract); and
- repeating the steps of delivering a positive pressure breaths and extracting respiratory gases.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 4-8, 10-13, 16-20 and 22-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Biondi et al. (US 5,377,671), as applied to **claims 1 and 14** above. Biondi et al. teaches a method comprising all limitations recited in **claims 4-8, 10-13, 16-20 and 22-24**, but does not expressly disclose the ranges of different system parameters, such as breath delivery time and rate, vacuum pressure and intrathoracic pressure levels. At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to optimize the most effective variables of this method to achieve optimal results, such as reducing intracranial pressures. Therefore, it would have been obvious to modify the method of Biondi et al. by utilizing the specific ranges of breath delivery time and rate, vacuum pressure and intrathoracic pressure levels because it is well known in the art to provide different parameters of breath delivery time

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and rate, vacuum pressure and intrathoracic pressure based on a specific patient's needs by "timing the respiratory gas introduction and extraction portions of the ventilatory cycle so as to be synchronous with portions of the cardiac cycle" in order to accomplish "reducing intrathoracic pressure of the patient" (column 2, lines 12-34). See *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Thursday from 8:30 am until 4:30 pm.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR 
November 29, 2004


Henry A. Bennett
Supervisory Patent Examiner
Group 3700